13. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96–hour LC_{50} on that species must also be provided.

14. Data are required on one estuarine/marine invertebrate species.

15. Data are required on estuarine/marine species if the product meets any of the following conditions:

i. Intended for direct application to the estuarine or marine environment.

ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

iii. If the acute LC_{50} or EC_{50} < 1 milligram/liter (mg/l).

iv. If the estimated environmental concentration (EEC) in water is ≥ 0.01 of the acute EC_{50} or LC_{50} or if any of the following conditions exist:

A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

B. Physicochemical properties indicate bioaccumulation of the pesticide.

C. The pesticide is persistent in water (e.g., half-life in water > 4 days).

16. Data are required on one estuarine/marine fish species.

17. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

18. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when any of the following conditions apply:

i. If the estimated environmental concentration (EEC) is ≥ 0.1 of the no-observed-effect level in the fish early-life stage or invertebrate life cycle test;

ii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

19. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are < 1,000; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is < 5 days at pH 5, 7 and 9.

20. Data are required based on the results of lower tier studies such as acute and chronic aquatic organism testing, intended use pattern, and environmental fate characteristics that indicate significant potential exposure.

21. Data are required if:

i. The half-life of the pesticide in the sediment is ≤ 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

ii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

22. Data are required if:

i. The estimated environmental concentration (EEC) in sediment is > 0.1 of the acute LC_{50}/EC_{50} values and

ii. The half-life of the pesticide in the sediment is > 10 days in either the aerobic soil or aquatic metabolism studies and if any of the following conditions exist:

A. The soil partition coefficient (Kd) is ≥ 50.

B. The log Kow is ≥ 3.

C. The Koc ≥ 1,000.

iii. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

23. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in concentrations which the Agency believes to be significant, either by runoff or erosion, because of its expected use or mobility pattern.

24. Data are required only when the formulation contains one or more active ingredients having an acute LD_{50} of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.

25. Required if any of the following conditions are met:

i. Data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.);

ii. Data from residual toxicity studies indicate extended residual toxicity.

iii. Data derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects.

26. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. Freshwater invertebrate and acute estuarine and marine organisms must also be tested with the EP or TEP using the same species tested with the TGAI.

§ 158.660 Nontarget plant protection data requirements table.

(a) *General.* Sections 158.100 through158.130 describe how to use this table to determine the nontarget plant

data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes only the general use patterns of aquatic food crops and aquatic nonfood.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.

(d) *Table.* The following table shows the nontarget plant protection data requirements. The table notes are shown in paragraph (e) of this section.

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern			Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry and Residential Outdoor		
Nontarget Area Phytotoxicity - Tier I						
850.4100	Seedling emergence	R	R	R	TEP	1, 2, 7
850.4150	Vegetative vigor	R	R	R	TEP	1, 2, 3, 7
850.4400 850.5400	Aquatic plant growth (algal and aquatic vascular plant toxicity)	R	R	R	TEP or TGAI	1, 2, 7
Nontarget Area Phytotoxicity - Tier II						
850.4100	Seedling emergence	CR	CR	CR	TEP	1, 4, 5, 7
850.4150	Vegetative vigor	CR	CR	CR	TEP	1, 3, 4, 5, 7
850.4400 850.5400	Aquatic plant growth (algal and aquatic vascular plant toxicity)	CR	CR	CR	TEP or TGAI	1, 4, 6, 7
Nontarget Area Phytotoxicity - Tier III						
850.4300	Terrestrial field	CR	CR	CR	TEP	1, 7, 8, 10
850.4450	Aquatic field	CR	CR	CR	TEP	1, 7, 8, 10
Target Area Phytotoxicity						
850.4025	Target area phytotoxicity	CR	CR	CR	TEP	1, 7, 9, 10

(e) *Test notes.* The following test notes apply to the table in paragraph (d) of this section.

1. Not required for contained pesticide treatments such as bait boxes and pheromone traps unless adverse effects reports are received by the Agency.

2. Not required for known phytotoxicants.

3. Generally not required for granular formulations. May be requested on a case-by-case basis.

4. Required for known phytotoxicants such as herbicides, desiccants and defoliants.

5. Required if a tested terrestrial species exhibits a 25 percent or greater detrimental effect in the Tier I study. When Tier II testing is required, the test species should be the species that showed detrimental effects in the Tier I testing.

6. Required if the tested aquatic species exhibits a 50 percent or greater detrimental effect in the Tier I study. When Tier II testing is required, the test species should be the species that showed detrimental effects in the tier I testing.

7. Not required for aquatic residential uses.

8. Environmental chemistry methods used to generate data must include the results of a successful confirmatory method trial by an independent laboratory.

9. Tests are required on a case-by-case basis based on the results of lower tier phytotoxicity studies, adverse incident reports, intended use pattern, and environmental fate characteristics that indicate potential exposure.

10. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

Subparts H–J [Reserved]

§§ 158.700–158.900 [Reserved]

Subpart K—Human Exposure

§ 158.1000 Applicator exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration (OSHA), provide adequate protection from risk under FIFRA for a particular pesticide use pattern, exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing prior to the initiation of studies.

(b) The Agency may accept surrogate exposure data estimations from other sources to satisfy applicator exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. In order to be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address applicator exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the applicator activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

§ 158.1010 Applicator exposure—criteria for testing.

Applicator exposure data described in paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if a product meets, as determined by the Agency, at least one of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from handling of the pesticide.

(b) *Exposure criteria.* (1) Dermal exposure may occur during the prescribed use.

(2) Respiratory exposure may occur during the prescribed use.

§ 158.1020 Applicator exposure data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the applicator exposure data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood crop, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food use, and indoor nonfood use. Occupational use patterns also include commercial (''for hire'') applications to residential outdoor and indoor sites.

(2) Residential use patterns include residential outdoor use and residential indoor use. These use patterns are limited to nonoccupational, *i.e.*, nonprofessional, pesticide applications.

(c) *Key.* R=Required; CR=Conditionally required; TEP=Typical end-use product.

(d) *Table.* The data requirements listed pertain to pesticide products that meet the testing criteria outlined in § 158.1010. The table notes are shown in paragraph (e) of this section.